4. THE CMS RULES FOR FORMULARIES

Background: How Do the CMS Formulary Rules Work?

Under Part D, plans can establish their own formularies and classification systems, subject to CMS' verification that they are not discriminatory. The MMA established the base requirement that at least two drugs be covered in each category and class. In regulations, CMS has stated that formularies must provide adequate coverage of the types of drugs most commonly needed by enrollees, as recognized in national treatment guidelines, and that they most offer complete treatment options for a variety of medical conditions. This general principle has been interpreted in a CMS guidance document that established the following rules:

1. At least one drug in each USP key drug type must be covered.
2. At least two drugs in each USP class must be covered.
3. All or substantially all drugs in the antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants, and antineoplastics classes must be covered (originally stated as a majority of drugs in these categories).
4. There should be appropriate access to drugs listed in widely accepted national treatment guidelines.
5. Drugs should only be on a higher tier only when therapeutically similar drugs are available on a lower tier.

In addition, CMS will check drug lists against risk adjustment categories to avoid drug selection and discrimination. Although these rules seem straightforward, there are many nuanced policy issues surrounding how drugs are counted. As described in the previous section, how differing forms or strengths of the same drug are treated can effect whether plans meet the formulary rules.

The sample list of drugs in the USP classification system includes 1134 separate pharmaceutical preparations. To meet CMS' requirements to cover two drugs in every pharmacologic class and one drug in every key drug type, a plan would have to cover 315 drugs. To also meet the requirement to cover "most or all" drugs in certain categories, plans will have to cover a total of about 425 drugs – just over a third of the drugs in USP's list.

The two tasks we addressed in this segment of the project are to consider how thoroughly these rules require plans to cover the drugs most commonly used by beneficiaries and whether formularies currently used in the private sector seem to meet the guidelines. We examined these questions in terms of four of CMS' minimum requirements (for the other requirements, CMS has not provided sufficient information to operationalize them for this analysis):

1. One drug per key drug type
2. Two drugs per drug class
3. Most or all of the drugs in certain categories (e.g., drugs to treat AIDS, atypical anti-psychotic drugs, and anti-depressants)

4. Cover at least some drugs on lower tiers

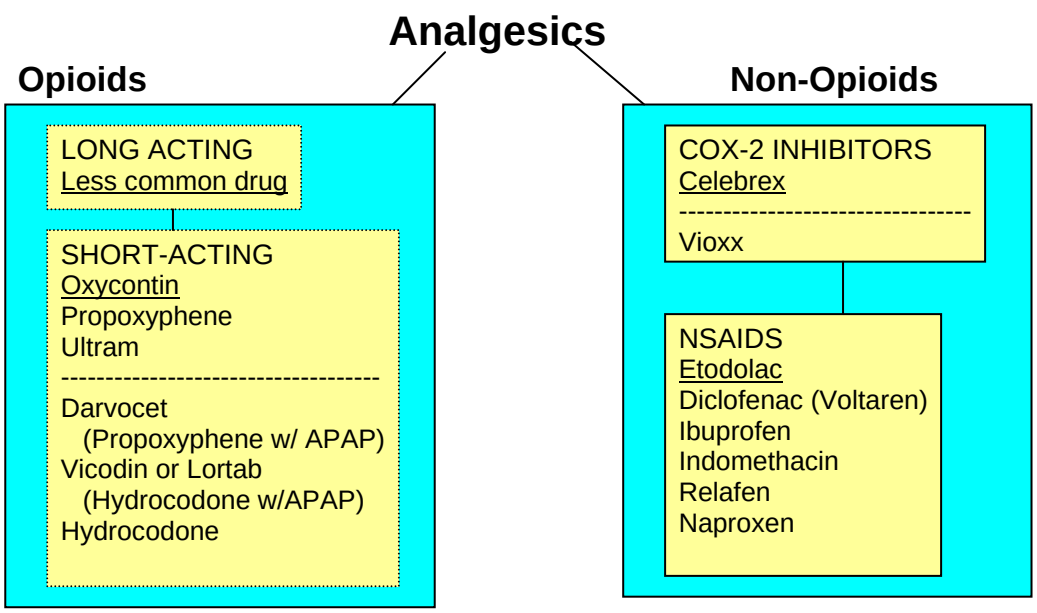
Coverage of Commonly Used Drugs Under CMS Rules

Using data from the 2001 MCBS, we identified all drugs with an estimated use of at least 500,000 prescriptions for all forms and strengths of the drug. We then determined whether a PDP implementing a formulary that met only the bare minimum CMS standards (2 drugs per class, 1 drug per key drug type, and a majority of drugs in certain categories) would cover these commonly used drugs. Although we do not necessarily expect PDPs to submit these bare-bones formularies, this analysis points out classes that may merit additional attention by CMS reviewers.

In 12 of 41 categories and in 28 of 146 classes, a minimally acceptable formulary based on the guidelines we can operationalize would not cover all the commonly used drugs. The main categories in which there were more commonly used drugs than the CMS minimum requirements were cardiovascular drugs, analgesics, anti-inflammatories, and gastrointestinal drugs.

As an example, Figure 7 shows a "minimally acceptable" scenario for the analgesic category. The USP system breaks analgesics into two pharmacologic classes, Opiods and Non-Opiods. Each of these classes is further broken into two key drug types: Long-Acting and Short-Acting Opiods, and Cox-2 Inhibitors and NSAIDs. In this case, a formulary would be required to cover one drug in each key drug type. This would automatically result in meeting the two drugs per class requirement.

Figure 7. Coverage of Analgesics in a Minimally Acceptable Formulary



- Listed drugs are from the most commonly used drugs by Medicare beneficiaries (MCBS 2001).
- Underlined drugs would be covered meeting key drug type standard.
- "Less common drug" indicates a slot for a drug not meeting our standard for commonly used drugs.
- Drugs below the dashed line are commonly used drugs that are not eligible for credit toward meeting formulary guidelines because they are off market (Vioxx), missing from the USP list (Hydrocodone) or combination drugs.

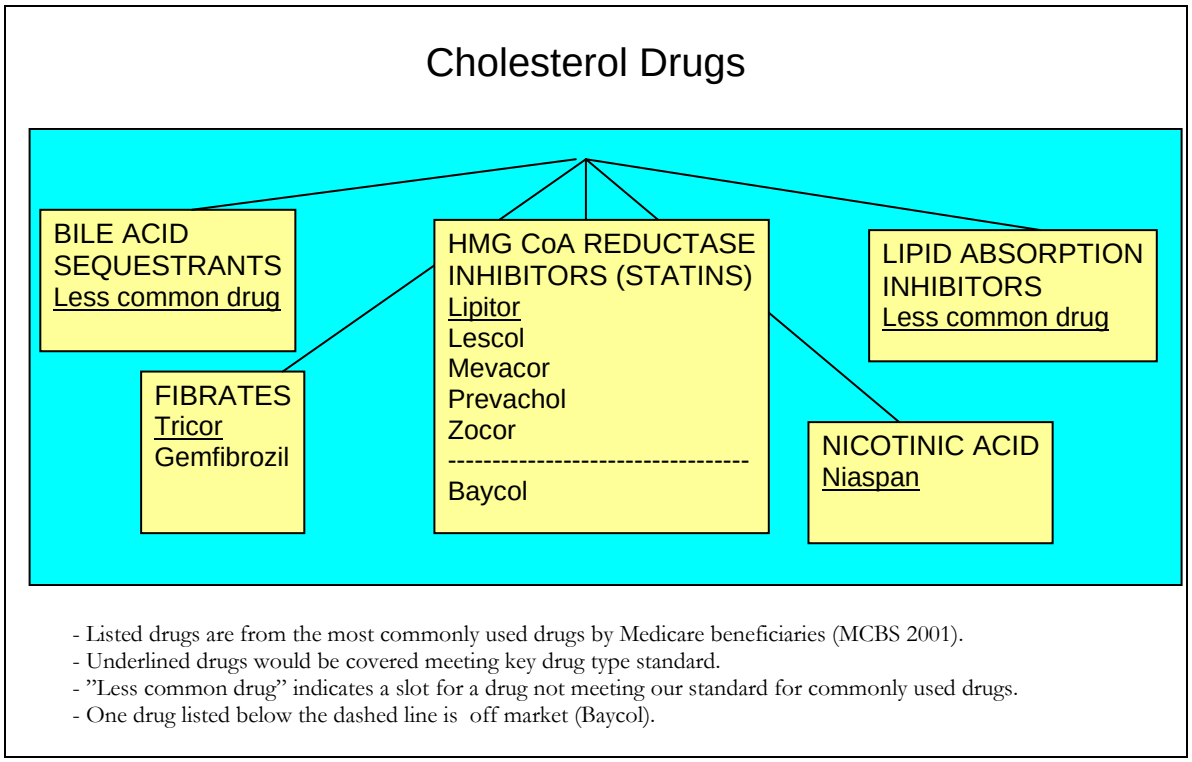
In the Long-Acting Opioids key drug type, there are no drugs that meet our definition of a commonly used drug. A minimally acceptable formulary would have to cover one "less common" drug in this key drug type. In the Short-Acting Opioids, there are three commonly used drugs on the USP list (Oxycontin, Propoxyphene, and Ultram). In this example, we assume our minimally acceptable formulary would cover only one of these drugs.

In addition, there are three drugs that meet our definition of a commonly used drug that are widely considered to be short-acting opioids, but that are not on the USP list. Two (Darvocet and Vicodin) are combination drugs, and Hydrocodone is not on the list for an unexplained reason. If a plan chose to cover these drugs, they would not count toward the minimum coverage requirements.

In the Cox-2 Inhibitors key drug type, Celebrex is the only commonly used drug on the USP list (not including Vioxx, which is now off the market). We assume that the minimally acceptable formulary would cover this drug. In the NSAIDs key drug type, there are six commonly used drugs (Etodolac, Diclofenac, Ibuprofen, Indomethacin, Relafen, and Naproxen). Again, a minimally acceptable formulary would have to cover only one of these drugs to meet CMS' most basic rules. If PDPs actually implemented such a formulary on a widespread basis, millions of beneficiaries might either have to change the drug they take or pay the full price of their drug out of pocket.

As a second example, we considered drugs used to treat high cholesterol (Figure 8). This is a pharmacologic class which is broken into five key drug types. The most heavily used key drug type in this class is Statins. Six statins meet our definition of a commonly used drug, but a minimally acceptable formulary in our example would only cover one of these six drugs.

Figure 8. Coverage of Cholesterol Drugs in a Minimally Acceptable Formulary



In the Fibrate key drug type, there are two commonly used drugs; a minimally acceptable plan would cover only one of these drugs. The Nicotinic key drug type has only one commonly used drug; a plan in our minimally acceptable scenario would cover this drug. Two of the key drug types (Bile Acid Sequestrants and Lipid Absorption Inhibitors) do not have any commonly used drugs; a plan would have to cover one less common drug in each of these classes.

Our analysis of several additional drug classes is available in Appendix E. In each, there are examples of classes or key drug types in which a minimally acceptable formulary would be able to meet the basic CMS rules but leave a commonly used drug uncovered. If plans regularly implemented such minimally acceptable formularies, there would be considerable impact on beneficiaries, either in terms of changing drugs or paying out of pocket to continue taking an off-formulary drug. However, as discussed below, there are reasons to believe such minimally acceptable formularies will not be widespread.

Policy Implications: Adequacy of Coverage under the CMS Rules

As this analysis shows, CMS's minimum coverage requirements could allow PDPs to omit many commonly used drugs from their formularies. However, there are several reasons why these commonly used drugs may be still be covered. First, further guidelines submitted by CMS may ensure coverage of additional drugs. For example, in June CMS clarified its policy on coverage of mental health and AIDS drugs. The original guideline said that a majority of drugs must be covered, while the new guideline says that "most or all" drugs in these classes must be covered.

Secondly, the broader CMS requirements would require that a therapeutically similar drug be covered in place of the off-formulary drug under the principle that drugs must be included to treat all diseases and health conditions. In some cases, this may lead plans to expand coverage in classes where drugs are not considered similar enough to be direct substitutes for one another.

Finally, in order to ensure a higher market share, PDPs may choose to cover more than the minimum number of required drugs. For instance, in hopes of attracting more cholesterol patients, and thus covering its fixed costs, a plan may opt for more generous cholesterol drug coverage. Nevertheless, some drugs will inevitably not be covered, forcing some beneficiaries to either switch drugs or to bear the full cost of their medication.

Would "Real World" Formularies Meet CMS Rules?

We examined four of the formularies in our study for whether they would meet four of CMS' minimum requirements. These formularies are based loosely on four of those studied in the earlier phase of this project – two FEHBP plans and two other private-sector formularies. We have chosen not to identify these formularies by name since we made adaptations to the actual formularies used. For example, as noted below, we have modified an open three-tier formulary to be a closed two-tier formulary with the third-tier drugs considered to be off formulary.

For each plan, we matched the drug names listed in the formulary to drug names in the USP. Because the USP lists only generic ingredient names, not brand names, this required translating brand names listed on each formulary into their generic equivalents. To do this we used both the FDA's NDC files and the Redbook. Once this match was complete, we determined whether the formulary had listed two drugs in each of USP's pharmacologic classes, one drug in each key drug type, and a majority of the drugs in the special classes highlighted by CMS.

Figure 9 shows some of the results from this analysis. The plans we studied fail to list one drug per key type for about a fifth to a quarter of all key drug types. They fail to list two drugs per class (or one when there is only one in the class) for about a quarter to a third of all classes.

Figure 9. How Do Four Formularies Fare Under CMS Formulary Requirements?

	# of Key Drug Types Failed	% of Key Drug Types Failed	# of Classes Failed	% of Classes Failed

Plan A	24	20%	49	34%
Plan L	26	22%	33	23%
Plan O	31	26%	58	40%
Plan I	31	26%	50	34%

There are two important caveats to this analysis. First, Plan A and Plan I are open 3-tier formularies. Plan A claims to explicitly place all drugs on a tier, but there are 75 drugs on the USP list that are not on the Plan A list. Plan I does not list any drugs on Tier 3; instead, all unlisted drugs are presumed to be on Tier 3. However, we did not automatically assign unlisted drugs to Tier 3 for either of these formularies. In effect, we tested CMS' fourth requirement by noting the classes in which these plans did not name any covered drugs. Although these plans actually do cover drugs in these classes, they are only at higher tiers. The plan would effectively fail CMS' rule that drugs can only be on a higher tier if a therapeutically similar drug is listed on a lower tier.

In addition, there were several hard-to-match categories where our analysis may have missed drugs. For example, dermatologics and ophthalmics include many drugs that come in multiple forms and are listed in multiple places in the USP scheme. To the extent that a formulary listed these drugs in only one place, without specifying which forms of the drugs it covered, we may have failed to link the drug with its match in the USP. Similarly, vaccines and therapeutic nutrients were listed by different names in formularies, making them difficult to match to USP if they were listed at all.

Beyond these caveats, important patterns do emerge in the types of classes and key drug types that plans failed. Many of the failed classes and types were clustered in a few categories, including antibacterials, antidementia, cardiovascular, and metabolic drugs. These are classes that may warrant special attention from formulary reviewers.

In addition, many of the commonly-failed key types and classes include only one drug. This highlights the importance of USP's decisions about whether to subdivide a category or class into very specific groups. In some cases, these specific groupings may provide important protection for beneficiaries who need access to a particular drug. In other cases, further review may be warranted to determine whether the subdivision is necessary.

Figure 10. Do Formularies Cover All Drugs in Required Classes?

	Drugs in USP	% of USP Drugs Listed on Formulary			
		Plan A	Plan L	Plan O	Plan I
Anticonvulsants	18	78%	89%	44%	50%
Antidepressants	24	75%	79%	67%	75%
Antineoplastics	53	6%	38%	36%	9%
Antipsychotics	18	72%	78%	61%	78%
Antiretrovirals	37	95%	73%	65%	68%
Immune Suppressants	16	56%	69%	19%	31%

The plans we studied also failed to list "all or substantially all" the drugs in required classes on their formularies (Figure 10). Even in Plan A, which claims to list all drugs, coverage exceeds 90% in only one category. In some cases, particularly anti-neoplastics, drugs may not be listed on the formulary because they are typically covered as inpatient drugs.

This analysis also gives some insight into CMS' fourth rule, that plans may only cover drugs on a third tier if a therapeutically equivalent drug is available on a lower tier. Plan A is the only formulary in our study that explicitly lists Tier 3 drugs on its formulary. In the Plan A formulary, two USP classes and six USP key drug types have drugs only on tier 3. As discussed above, Plans A and I would also fail this test in the classes above in which they failed to list enough drugs to meet CMS' rules.

Policy Implications: Will "Real World" Formularies Pass the CMS Tests?

According to our analysis, formularies in use today would not meet the CMS tests for adequacy without some adjustments. Presumably, it will not be too difficult for these plans to make the necessary adjustments by adding a few drugs to their formularies, or moving them to lower tiers.

Since utilization is heavily concentrated in a few categories and classes, formulary decisions for these specific groups of drugs have a disproportionate influence on beneficiaries' need to switch drugs or pay more out-of-pocket costs. Even if a plan meets CMS' minimum rules in these classes, large numbers of beneficiaries may be affected when other drugs are uncovered. In addition, some categories and classes are quite diverse; the rule requiring just two to be covered may not adequately ensure all needs are satisfied.

Conversely, some categories and classes have just one or a few rarely-used drugs. Lack of coverage for these rarer drugs can still cause a formulary to "fail." Although these cases may not affect a lot of beneficiaries, the intent is to protect beneficiaries whose drugs are not commonly used.